REMARKS

Claims 30 and 36-41 are pending in the subject application upon entry of the amendments. Claims 1-29 and 31-35 have been cancelled without prejudice or disclaimer in view of the Restriction Requirement. Favorable reconsideration in light of the amendments and the remarks which follow is respectfully requested.

I. Amendments

Amendments to claim 30 are fully supported by the Specification. For examples Figures 1 and 4 and US. Pat. Pub. 2007/0178436 ¶¶ [0026]-[0041] describe the manner that whole blood is withdrawn from a patient, treated, and returned to the patient as reconstituted whole blood. Figures 1 and 4 show a closed system; therefore, it is clear to a person skilled in the art that whole blood is removed from a patient at the same time as reconstituted whole blood is being returned to the patient.

New claim 39 is fully supported by the Specification, for example, Figure 4. Figure 4 shows that blood is removed and returned to the patient using different tubes.

New claims 40 and 41 are fully supported by the Specification. For Example, since Figures 1 and 4 show a closed system, it is clear to a person skilled in the art that blood is removed from and returned to a patient at the same rate. The rate of whole blood removal of 30 to 150 ml/L is supported by the Specification, for example, US. Pat. Pub. 2007/0178436, ¶ [0013].

New claims 42 and 43 are fully supported by the Specification. For Example, paragraphs [0016] and [0013] of US. Pat. Pub. 2007/0178436.

II. Rejection of Claims 30 and 36-38 Under 35 U.S.C. § 112, Second Paragraph

Claims 30-38 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, the Examiner states that the term "establishing a circulatory system" is unclear. Claim 30 is amended specific act for removing whole blood from a patient, separating and treating such blood including adding methylene blue and irradiating, and returning reconstituted whole blood to the patient. The term "establishing a circulatory system" is no longer recited in the claims. As shown in, for Example, Figure 4 of the Specification, blood is removed from a patient, treated, and returned to a patient in a continuous circular loop.

The Examiner also cites an alleged inconsistent use of several terms in claim 30

including circulatory blood, whole blood, "at least virus in the plasma," etc. The claims are amended to describe how each "blood" product is formed. That is, whole blood is removed from a patient, an anticoagulant is added to the whole blood and separated into plasma and red blood cells, and the plasma is then light treated and recombined with the red blood cells to form reconstituted whole blood. As such, it is believed that the terminology recited in claim 30 is clear.

Therefore, it is respectfully requested that the rejection of claims 30 and 36-38 under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. Rejection of Claims 30 and 36-38 Under 35 U.S.C. § 103(a)

Claims 30 and 36-38 stand rejected under 35 U.S.C. §103(a) over of Saalmann (WO 00/59551), Park et al (U.S. 5,516,629), Morrison (U.S. 3,677,667), Broussard et al (U.S. 3,989,740), Smith et al (U.S. 3,223,642), Fantini et al (Applied Optics, 1994, pp. 5204-5213), Prahl (html address stated in Office Action), and Sikurova (Laser Physics, 2003, pp. 217-221).

Saalmann is the only document relating to a system or method for treating blood from a patient. Park et al appears to relate to the light inactivation of viruses with light; however, Park et al has no teachings regarding a system or method for directly treating the blood of a patient. Morrison appears to relate to a peristaltic pump. Broussard et al, Fantini et al, Prahl, and Sikurova appear to relate to the absorption properties of methylene blue. Smith et al appears to relate to the use of Fuller's earth for the removal of methylene blue.

Saalmann appears to teach a system where blood is removed from container 4 through a valve 6 and a conduit 8 en route to an irradiation unit 34. Saalmann teaches that "blood can be pumped in the conduit 8 in both directions." Saalman, page 8, line 1. After treatment, "blood is returned from the plasma container 36 . . . [via] conduit 8 with the valves in the appropriate position to container 4 or the blood circulation of a patient." Saalman, page 8, lines 16-20.

That is, Saalman teaches a system where blood is removed, treated, and then returned in a batch-wise fashion. Saalmann does not teach a system where blood is continuously removed, treated, and transfused back into a patient in a continuous loop. Rather, Saalman discloses a system where blood is removed and separated into components and the "red corpuscles and blood platelets are immediately infused back

in to the patient." Saalman, page 9, lines 17-18. The remaining blood components are subjected to irradiation and returned to the patient at a later time. As such, Saalmann does not teach nor suggest "removing the whole blood from the patient or other source and transfusing the reconstituted whole blood into the patient or other source are done simultaneously in time." Since the red blood cells and plasma are returned to the patient at different times, Saalman further does not teach transfusing reconstituted whole blood into a patient after light treatment. Rather, Saalman teaches transfusing separate blood components back into the patient instead of whole blood.

As such, Saalmann teaches a system where blood is removed, treated, and then reserved in a batch-wise fashion. In contrast, the present claims involve a system where blood is continuously removed from a patient, treated, and transfused back into the patient so as to form a continuous blood circulation, as described above. Thus, the methods of Saalmann are essentially suitable for blocking the spread of a virus between a blood donor and a blood recipient, which cannot be used in therapy where the virus is systematically eliminated from a patient's blood volume. The methods of the present claims can be used in the treatment of virus diseases by substantially inactivating all virus particles present in a patient's total blood volume.

The advantages for the above distinction lie in two aspects. First, the safety of the present claims is higher. The blood removed from a patient by the methods of the present claims forms a circulation system with the blood inside the body of the patient, such that all steps are performed in a sealed system isolated from the outside environment, which avoids the exposure of the blood to the environment or unnecessary preservation of the blood and thereby reduces the risk of cross contamination. In addition, since the blood belongs to the same person rather than being transfused from others, the chance for being infected and the burden for matching the blood type are reduced or eliminated.

Second, the present claims can produce higher efficiency for virus activation. Even though the blood can be removed from and immediately returned to the same subject by Saalmann's method, its efficiency is extremely low as compared to the continuous circulation method of the present claims. Saalmann's method requires multiple intermittent removal of blood for treatment with the amount of blood treated batch-wise each time being much lower than the total blood amount within the body of the subject, due to the limited endurance for blood loss. Thus, even if the blood being

removed from the body is treated such that the concentration of the virus in said portion of blood is reduced to a negligible level, the drop of the overall concentration of the virus is not remarkable after said portion of blood being transfused back into the body, as the majority of blood within the body has not been subjected to the virus inactivation. Accordingly, it is impossible to adopt the multiple intermittent removal of blood in therapy as taught in Saalmann. However, the present claims involve a continuously dynamic inactivation, which removes blood while the treated blood from the same subject is continuously returning to the body of the subject in time. That is, a blood circulation is formed inside and outside the body. Through the dynamic treatment of the blood outside the body, the concentration of the virus in the blood circulation is decreased within several tens of minutes, and thus the efficiency is extremely high. Thus, the blood is subjected to repeated virus inactivation treatment, which achieves the object of treating the virus diseases.

Another distinction between the present invention and Saalmann lies in that Saalmann is silent of mixing photosensitizer methylene blue with the separated plasma with a peristaltic pump, illuminating with a LED for 60 seconds, and removing the photosensitizer methylene blue with attapulgite. The Examiner alleges that above features are disclosed in pieces of certain documents. The peristaltic pump not only ensures the flowability of the circulating blood, but also controls the amount of methylene blue added such that a dynamic balance can be maintained by making the rate for transferring methylene blue as 1% of the rate for transferring the plasma. In view of the mechanism of using photosensitizer in virus inactivation, the effect for removing virus is increasing with the rise of the amount of methylene blue. However, the removal the photosensitizer will be troublesome if the concentration thereof is too high.

The features with respect to the continuous and sealed blood circulation treatment system of the present claims, controlling of the concentration of methylene blue to 1% is an unobvious claim feature achieved in consideration of both of the above factors. That is, none of the cited documents including Smith teach or suggest controlling the concentration of methylene blue to 1%. Saalmann does not involve the active re-circulation of blood, let alone controlling the flow rate to specific rates. The cited secondary documents do not fix the problem by disclosing controlling the adding amount of photosensitizer.

With respect to the light source, since the present claims relate to the illumination of circulated blood, the type of the light source and the duration of the illumination will influence the virus inactivation effect of the blood circulation therapy system. Fantini et al only teaches that a LED may have a virus inactivation effect; however, Fantini et al does not imply that a LED can be used in dynamic inactivation of the virus in flowing blood. As to the 60-second duration of the illumination recited in the present claims, the duration is determined by considering the transferring rates of the plasma and methylene blue in the whole circulation, which are controlled by the peristaltic pump. Since said duration is not disclosed in any of the cited documents, none of the cited documents teach or suggest to an ordinary skilled person in the art that both satisfied activation effect and flowability of the circulating blood can be obtained by maintaining a 60-second duration of illumination without extensive experimentation.

With respect to the recitation of attapulgite, Smith only teaches that said substance can be used in filtration. *See* Smith et al, Example XIV. There is no teaching that attapulgite can be used to chemically absorb methylene blue in a biological material. Example XIV of Smith et al appears to only teach that attapulgite is used to filer to physically remove particulate material to leave a viscous substance during the synthesis of fluorinated silicon compounds as described therein. Smith et al does not teach the selection of any material for the absorption material for methylene blue in a blood circulation therapy system. A skilled person in the art would commonly use activated carbon, which has been known to meet the requirement for pharmaceutical uses, as the absorption material for methylene blue in the method of Saalmann. Since Saalmann does not relate to a blood circulation and Smith does not relate to the absorption of methylene blue from a blood circulation, a skilled person in the art cannot obtain the technical solution of applying attapulgite in the blood circulation to remove methylene blue without undue experimentation.

Therefore, it is respectfully requested that the rejection of claim 30 and 36-38 under 35 U.S.C. § 103(a) be withdrawn.

IV. Petition for Extension of Time

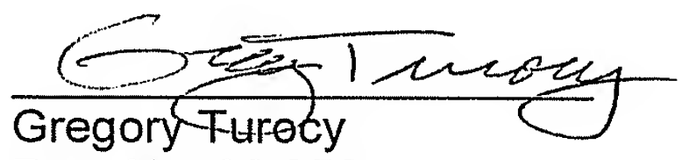
A request for a two-month extension of time is hereby made. Payment is made *via* the EFS filing system.

In the event any fees are due in connection with this document, the Commissioner is authorized to charge those fees to Deposit Account No. 50-1063.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicants' undersigned representative at the telephone number below.

Respectfully submitted,

Turocy & Watson, LLP



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